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March 12, 1998

By Hand

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

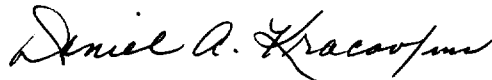
Re: Pharmanex, Inc. Docket No. 97P-0441

Dear Sir or Madam:

Enclosed please find a letter from William E. McGlashan, Jr. to the National Consumers League for inclusion in the above-referenced docket:

If you have any questions, please do not hesitate to call.

Sincerely,



Daniel A. Kracov
Counsel to Pharmanex, Inc.

Enclosure

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PHARMANEX

A Natural Healthcare Company

William E. McGlashan, Jr.
President

March 11, 1998

Ms. Linda F. Golodner
President
Mr. Brett Kay
Program Associate, Health Policy
National Consumers League
1701 K Street, NW
Suite 1200
Washington, DC 20006

Re: National Consumers League Comments on
Cholestin™ Dietary Supplement

Dear Ms. Golodner and Mr. Kay:

I was disappointed to read the comments of the National Consumers League (NCL), dated January 30, 1998, to the Food and Drug Administration regarding Pharmanex, Inc's Cholestin™ red yeast rice dietary supplement. In the comments, NCL challenged the scientific underpinnings of the statements of nutritional support for Cholestin™ as limited and lacking in methodological rigor. Frankly, NCL's position is not consistent with the facts.

Pharmanex prides itself on its commitment to scientific rigor. It has invested significant resources into research and development to ensure the excellence of its product and validity of its statements of nutritional support. Pharmanex has relied upon a broad range of scientific studies to demonstrate the cholesterol-lowering effect of Cholestin™. These include two predictive animal models that were published in a peer-reviewed scientific journal, as well as numerous clinical trials, including both controlled and open-label trials that assessed the safety and functionality of Cholestin™. Of the clinical trials, one major randomized multi-center trial was accepted for publication in a peer-reviewed American journal, as was a randomized double-blind controlled trial. Each of these trials involved hundreds of patients. In addition, a symposium on Cholestin™ was held recently in China, at which the results of an additional four animal studies and fourteen human studies confirming that the statements of nutritional support for Cholestin™ -- promotion and maintenance of healthy cholesterol levels -- were reported. Finally, a double-blind, randomized, placebo-controlled prospective study conducted at a major U.S. university found that Cholestin™ significantly reduces cholesterol levels



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without significant adverse effects. This study has been submitted for publication in a major peer-reviewed journal.

What is most disturbing about the NCL's comments is that Pharmanex has in the past communicated all of the above information to the NCL, and offered to make these studies available for review. NCL declined the opportunity to review these data, and instead proceeded to submit its unfortunate comments to the Food and Drug Administration.

The body of scientific evidence supporting the safe and beneficial use of Cholestin™ as a dietary supplement is a prime example of what the Dietary Supplement Health and Education Act was intended to promote. This important statute was made a reality by the millions of consumers who fought for access to alternative products for promotion of good health. Rather than adhering to a "pharmaceuticals at any cost" philosophy, NCL should heed the call of these consumers and recognize the significant efforts made by Pharmanex to produce responsible dietary supplement products.

I believe that with a more complete understanding of our data the NCL would support the use of our product. Thus, Pharmanex wishes to reiterate its offer to provide the NCL with an opportunity to review the studies demonstrating that Cholestin™ can safely promote and maintain healthy cholesterol levels. I hope that the NCL will take advantage of this opportunity to understand this important product, and to base its position on a complete review of the facts.

Sincerely,

William E. McGlashan, Jr.

cc: Docket No. 97P-0441 (Pharmanex, Inc.)